PATENT

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Matter of the Application of:	GANTZ et al.	
SERIAL NO.:	10/518,811	Group Art Unit: 3766
Filed:	July 11, 2005	Examiner: CHU, Michael A.
Entitled:	**COCHLEAR IMPLANT ELECTRODE ARRAY**	
Docket No.:	22409-00113-US	

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REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

In response to the Supplemental Examiner's Answer mailed September 24, 2009, Appellants submit this reply brief under 37 C.F.R. § 41.41.

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I. STATUS OF CLAIMS

Claims 1-4, 6, 8-10, 12, 13, 22-25, and 36-43 are currently pending in the present application, Application Number 10/518,811. Claims 5, 7, 11, 14-21 and 26-35 were previously cancelled. Claims 1-4, 6, 8-10, 12, 13, 22-25, and 36-43 have been finally rejected and, therefore, are subject to appeal.

II. STATUS OF AMENDMENTS

The Examiner indicated in the Supplemental Examiner's Answer that the amendment after final rejection has not been entered. Appellants note that the paper filed on January 4, 2008 did not contain any claim amendments. Presumably, this is why the Examiner did not indicate in the Advisory Action mailed January 31, 2008 that the amendments would not be entered, as provided for by the Advisory Action form. Because the paper filed on January 4, 2008 did not contain any claim amendments, Appellants submit that this issue is moot.

III. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether the Examiner improperly rejected independent claims 1, 22 and 38 and dependent claims 2-4, 6, 8-10, 13, 25, 36, 37, 39 and 41-43 under 35 U.S.C. § 103(a) as unpatentable over WO 00/69513 to Kuzma in view of U.S. Patent No. 5,143,090 to Dutcher.

IV. ARGUMENT

Claims 1-4, 6, 8-10, 13, 25, 36, 37, 39 and 41-43

The Examiner's rejections of independent claims 1, 22 and 38 and dependent claims 2-4, 6, 8-10, 13, 25, 36, 37, 39 and 41-43 under 35 USC §103(a) as being unpatentable over WO00/69513 to Kuzma ("Kuzma") in view of U.S. Patent No. 5,143,090 to Dutcher ("Dutcher") should be reversed at least because: (A) the Examiner has failed to provide an adequate reason to combine Kuzma and Dutcher when the device of Kuzma is inserted through the round window because (1) Kuzma teaches away from the combination when the device is inserted through the round window, and (2) the proposed combination would render the device of Kuzma unsatisfactory for its intended purpose when inserted through the round window; and (B) the Examiner has failed to provide an adequate reason to combine Kuzma and Dutcher when the device of Kuzma is inserted at an angle through a bone structure because (1) the Examiner has failed to show that the modified device would achieve the benefit proposed by the Examiner when the device is inserted at an angle, and (2) substantial modifications would be required to achieve the benefit proposed by the Examiner.

As stated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." (127 S.Ct. 1727, 1741 (2007).) The Supreme Court recognized that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some ***articulated reasoning with some rational underpinning to support the legal conclusion of obviousness***." (*See KSR*, 127 S.Ct. at 1741

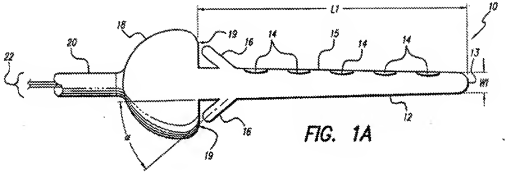
(citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006); emphasis added.) The Examiner, however, has failed to provide this required reasoning with a rational underpinning.

In the Supplemental Examiner's Answer, the Examiner repeated the assertion from the Final Office Action that Kuzma teaches all limitations of previously presented in independent claims 1, 22 and 38 other than the feature of "an anchor to prevent rotation." (*See*, Supplemental Examiner's Answer, pgs. 4-6.) The Examiner further alleged it would have been obvious to combine Dutcher with Kuzma because "Dutcher teaches using a porous polyester fiber mesh . . . in order to enhance tissue ingrowth to firmly fix the lead to target tissue. . . . Therefore it would have been obvious… to include the mesh of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix target tissue. The Office notes that the mesh material in the now modified device of Kuzma serves as an anchor configured to prevent rotation of the carrier along the longitudinal axis of the carrier." (*See*, Supplemental Examiner's Answer, pg. 4.) The Examiner makes this argument with respect to each of Appellants' independent claims 1, 22 and 38. (*See*, Examiner's Answer, pgs. 4-6.)

In the rejections noted above, the Examiner relied upon an electrode array 10 disclosed by Kuzma. Kuzma discloses two different methods of inserting electrode array 10. (*See*, Kuzma, pg. 8, lns. 3-5, and pg. 9, lns. 5-6.) Appellants will briefly describe each of these insertion methods and separately explain why the Examiner's asserted reason for making the proposed combination of Kuzma and Dutcher is inadequate with for each of these insertion methods.

With regard to the first method, Kuzma discloses that "[a]s seen in FIG. 2, the electrode array 10 may be inserted into the basal region 14 through a narrow slit 42 (FIG. 4) made in the

round window membrane (round window) 40." (*See*, Kuzma, pg. 8, lns. 11-13; and FIG. 2, reproduced below.) Kuzma discloses that "[t]he electrode array 10 is inserted through the slit 42 until the flaps or tines 16 have passed through the slit into the basal region 34, and the shoulder 19, formed by the head 18, rests against the middle-ear side of the round window membrane 40." (*See*, Kuzma, pg. 8, lns. 13-16; and FIGS. 1A and 2, reproduced below.) Thus, in the insertion method of FIG. 2, round window 40 is the "target tissue" described by the Examiner in the above quotation from the Supplemental Examiner's Answer. (*See*, Kuzma, pg. 8, lns. 13-16; and FIG. 2.)



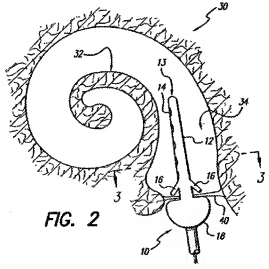


FIG. 1A and 2 of Kuzma

With regard to the second method, Kuzma discloses that "[t]he alternate approach shown in FIG. 5 has the electrode array 10 being inserted into the basal region 34 through a side slit made near the round window membrane. Such side slit is made at the bottom of a cavity 44, which cavity 44 is made in the bone structure adjacent the cochlea 30." (*See*, Kuzma, pg. 9, lns. 13-16; and FIG. 5, reproduced below.) Thus, in the insertion method of FIG. 5, the "target tissue" is the bone structure adjacent the cochlea, and head 18 of Kuzma's device is oriented at an angle with respect to that "target tissue." (*See*, Kuzma, pg. 9, lns. 13-16; and FIG. 5.)

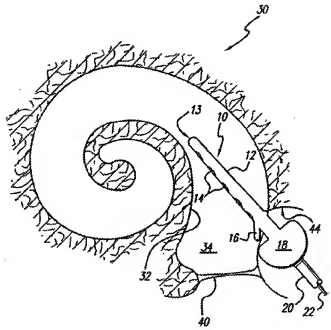


FIG. 5

FIG. 5 of Kuzma

In the Supplemental Examiner's Answer, the Examiner states that "adding the mesh of Dutcher to the invention of Kuzma would more firmly fix the electrode array to the target tissue than the features of Kuzma alone. The mesh of Dutcher enhances the ability to secure the

electrode array firmly to target tissue. Thus, there is motivation to combine Kuzma with Dutcher because the combination offers an improvement in security of attachment to target tissue." (*See*, Supplemental Examiner's Answer, pg. 9.) However, the Examiner's reasoning in support of making the proposed combination of Kuzma and Dutcher is not adequate for either of the insertion methods described above.

As will be discussed further below, the Examiner's reasoning is inadequate when the device of Kuzma is inserted via the first insertion method because Kuzma teaches away from the combination when Kuzma's device is inserted through the round window. Moreover, the proposed combination would render Kuzma's device unsatisfactory for its intended purpose when inserted through the round window. As will also be discussed further below, the Examiner's reasoning is inadequate when the device of Kuzma is inserted via the first insertion method because the Examiner has failed to show that the modified device would achieve the benefit proposed by the Examiner when the device is inserted at an angle. Moreover, substantial modifications would be required to achieve the benefit proposed by the Examiner when the device is inserted at an angle.

Thus, because the Examiner's reasoning in support of making the proposed combination of Kuzma and Dutcher is not adequate for either of the insertion methods described above, the rejections noted above should be reversed.

A. The Examiner has failed to provide an adequate reason to make the proposed combination of Kuzma and Dutcher when the device is inserted through the round window via the first insertion method of Kuzma

1. Kuzma teaches away from adding the mesh of Dutcher to the device of Kuzma when the Kuzma device is inserted through the round window via the first insertion method of Kuzma

Kuzma teaches away from the Examiner's asserted reason for making the proposed combination of Kuzma and Dutcher when the Kuzma device is inserted through the round window, and thus the Examiner has failed to provide an adequate reason for making the proposed combination of Kuzma and Dutcher when the Kuzma device is inserted through the round window.

As noted above, the Examiner proposes combining Dutcher and Kuzma because "Dutcher teaches using a porous polyester fiber mesh . . . in order to enhance tissue ingrowth to firmly fix the lead to target tissue. . . . Therefore it would have been obvious… to include the mesh of Dutcher with the device of Kuzma, ***for the purpose of enhancing tissue ingrowth to firmly fix target tissue***." (*See*, Supplemental Examiner's Answer, pg. 4; emphasis added.) As discussed above, in Kuzma's first insertion method, the "target tissue" is round window 40. (*See*, Kuzma, pg. 8, lns. 13-16; and FIG. 2.) However, Kuzma teaches away from firmly fixing head 18 of the Kuzma device to round window 40.

Kuzma teaches that the function of the round window is to vibrate, and that the vibration of the round window is part of the normal hearing process in the cochlea. (*See*, Kuzma, pg. 9, lns. 10-13, and pg. 3, lns. 6-8.) Kuzma teaches away from destroying this vibrating function of the round window membrane and thereby impeding normal hearing processes in regions other than the basal end of the cochlea. For example, Kuzma states that "[i]t is a further feature of the

invention to provide an electrode array suitable for insertion into the basal end of the scala tympani duct of a human cochlea ***without destroying the function of the round window membrane***, and without causing fluid to escape from the scala tympani duct, thereby allowing normal hearing processes (fluid motion activation of hair cells) to occur in regions other than the basal end of the cochlea." (*See*, Kuzma, pg. 4, lns. 23-28; emphasis added.)

Kuzma also teaches that the functionality of the round window is reduced by head 18 being placed against the round window. Kuzma discloses that "an alternate method of inserting the electrode array 10 into the basal region 34 of the scala tympani duct is illustrated" in FIG. 5 of Kuzma, and that "[t]his alternate method involves leaving the round window membrane 40 intact without making a slit therein, and without having the head 18 of the electrode 10 placed against it. ***This allows the round window membrane to more effectively perform its intended function during normal hearing of vibrating in response to sensed acoustic waves*** . . . ." (*See*, Kuzma, pg. 9, lns. 5-11 (emphasis added); and FIGS. 2 and 5, reproduced above.) Thus, Kuzma teaches that merely placing head 18 against the round window impedes the round window's performance of its vibrating function for normal hearing. Accordingly, Kuzma teaches away from firmly fixing head 18 to the round window, since firmly fixing head 18 to the round window would limit the round window's vibrating function even more severely than placing head 18 against the round window. Thus, firmly fixing head 18 to the round window would degrade normal hearing in a recipient of a device obtained through the Examiner's proposed combination of Kuzma and Dutcher.

Accordingly, Kuzma teaches away from firmly fixing head 18 to the round window and therefore teaches away from "enhancing tissue ingrowth to firmly fix target tissue" when Kuzma's device is inserted through the round window. (*See*, Supplemental Examiner's Answer,

pg. 4.) Thus, because "enhancing tissue ingrowth to firmly fix target tissue" is the Examiner's asserted reason for making the proposed combination of Kuzma and Dutcher, the Examiner's reason for combining Kuzma and Dutcher is inadequate when Kuzma's device is inserted through the round window. (*See*, Supplemental Examiner's Answer, pg. 4.) Thus, the Examiner's proposed combination is improper with regard to the first insertion method of Kuzma.

2. Adding the mesh of Dutcher to the device of Kuzma would render the device unsatisfactory for its intended purpose when inserted through the round window via the first insertion method of Kuzma

As discussed above, the Examiner's proposed combination of Kuzma and Dutcher would result in a device that would degrade normal hearing in a recipient when the device is inserted through the round window. Thus, because Kuzma's device is intended to allow normal hearing to occur in at least some regions of the cochlea, the Examiner's proposed combination would render the Kuzma device unsatisfactory for its intended purpose when inserted through the round window. (*See*, Kuzma, pg. 9, lns. 25-30.) The Manual of Patent Examining Procedure (MPEP) makes clear that "[i]f a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." (*See*, Manual of Patent Examining Procedure, §2143.01(V) (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).) .

The device of Kuzma is intended to be used in conjunction with the normal hearing process of a recipient. (*See*, Kuzma, pg. 4, lns. 23-28.) For example, Kuzma discloses that "[i]t is a further feature of the invention to provide an electrode array suitable for insertion into the basal end of the scala tympani duct of a human cochlea without destroying the function of the

round window membrane, and without causing fluid to escape from the scala tympani duct, ***thereby allowing normal hearing processes*** (fluid motion activation of hair cells) ***to occur*** in regions other than the basal end of the cochlea." (*See*, Kuzma, pg. 4, lns. 23-28; emphasis added.) Kuzma also specifically identifies that retention of normal hearing processes as a benefit of Kuzma's device, stating that "[i]t is further seen that the electrode array 10 of the invention may be inserted into the basal end of the scala tympani duct of a human cochlea ***without destroying the function of the round window membrane***, and without leaving an open hole through which fluid may escape from the scala tympani duct. ***This advantageously allows normal hearing processes*** (fluid motion activation of hair cells) ***to occur*** in regions other than the basal end of the cochlea." (*See*, Kuzma, pg. 9, lns. 25-30; emphasis added.)

However, as discussed above, firmly fixing head 18 to the round window would limit vibration of the round window and thereby degrade normal hearing processes in a recipient of the device. Thus, firmly fixing head 18 to the round window would make the Kuzma device unsuitable for its intended purpose when inserted through the round window. Thus, the Examiner is incorrect in asserting in the Supplemental Examiner's Answer that "the device of Kuzma is not rendered unsatisfactory, because the features of Kuzma cooperate in tandem with the added mesh of Dutcher. There is no loss of functionality." (*See*, Supplemental Examiner's Answer, pg. 9.) Rather, as discussed above, there would be a loss of functionality because firmly fixing head 18 to the round window would limit vibration of the round window and thereby degrade normal hearing processes in a recipient of the device.

Accordingly, firmly fixing head 18 to the round window is not an adequate reason for making the proposed combination of Kuzma and Dutcher when the device is inserted through the round window. For this additional reason, the Examiner's proposed combination is improper

with regard to the first insertion method of Kuzma.

B. The Examiner has failed to provide an adequate reason to make the proposed combination of Kuzma and Dutcher when the device is inserted at an angle via the second insertion method of Kuzma

1. The purpose for which the Examiner proposes combining Kuzma and Dutcher would not be achieved by the proposed combination when the device is inserted at an angle via the second insertion method of Kuzma

As noted above, the Examiner states that "it would have been obvious… to include the mesh of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix target tissue." (*See*, Supplemental Examiner's Answer, pg. 4.) However, the Kuzma device modified with the mesh of Dutcher would not achieve this purpose when inserted at an angle via the second insertion method of Kuzma because, when modified as proposed by the Examiner, the mesh would not make sufficient contact with the "target tissue" to "firmly fix" the device to that tissue.

As noted above, Kuzma states that "[t]he alternate approach shown in FIG. 5 has the electrode array 10 being inserted into the basal region 34 through a side slit made near the round window membrane. Such side slit is made at the bottom of a cavity 44, which cavity 44 is made in the bone structure adjacent the cochlea 30." (*See*, Kuzma, pg. 9, lns. 13-16; and FIG. 5, reproduced above.) Thus, in the insertion method of FIG. 5, the "target tissue" is the bone structure adjacent the cochlea, and head 18 of Kuzma's device is oriented at an angle with respect to the "target tissue." (*See*, Kuzma, pg. 9, lns. 13-16; and FIG. 5.)

The Examiner cites netting 117 described in column 5 of Dutcher. (*See*, Supplemental Examiner's Answer, pg. 4.) As shown in FIGS. 5 and 6 of Dutcher, netting 117 is relatively flat. (*See*, Dutcher, FIGS. 5-6, reproduced below.) Indeed, Dutcher describes an apparently similar

netting 27 as "generally flat." (*See*, Dutcher, col. 4, ln. 5; and FIGS. 1-3; FIG. 3 is reproduced below.) In the Supplemental Examiner's Answer, the Examiner states that "with either embodiment shown in Figures 2 or 5 of Kuzma, it is a simple modification to add the mesh of Dutcher, since the mesh is flexible and conforms to surrounding tissue, regardless of insertion angle." (*See*, Supplemental Examiner's Answer, pg. 10.)

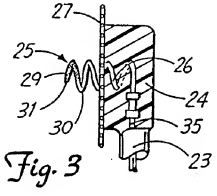
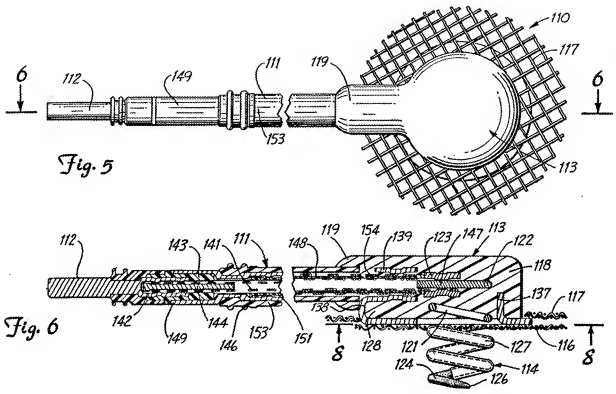


FIG. 3 of Dutcher



FIGS. 5 and 6 of Dutcher

The Examiner does not clearly state where the mesh from Dutcher would be placed on the Kuzma device in the proposed combination. Assuming for the sake of argument that it could be mounted on shoulder 19, when the Kuzma device is inserted at an angle, as shown in FIG. 5 of Kuzma, the full surface of shoulder 19 does not even contact the surrounding bone structure. (*See*, Kuzma, FIGS. 1A and 5, reproduced above.) Rather, as shown in FIG. 5 of Kuzma, only one corner of shoulder 19 makes contact with the surrounding bone structure. (*See*, Kuzma, FIG. 5, reproduced above.) Thus, mesh added to shoulder 19 of Kuzma would make only tangential contact between shoulder 19 and the bone structure.

Additionally, Dutcher teaches that netting 117 extends outwardly from head 113 of the Dutcher device, and FIG. 6 of Dutcher shows netting 117 extending only a relatively small amount beyond head 113. (*See*, Dutcher, col. 5, lns. 24-27; and FIG. 6, reproduced above.) However, even if mesh added to Kuzma extends a relatively small amount past shoulder 19, such relatively small extensions would likely only make substantial contact with the bone structure adjacent the edge of shoulder 19 where the mesh is already making the above-described tangential contact with the bone structure. This tangential contact with the bone structure, even with the small extension of mesh, would not be sufficient to "firmly fix" the device of Kuzma to the bone structure. Thus, the Examiner has failed show that the purpose for which the Examiner proposes combining Kuzma and Dutcher would be achieved by the proposed combination when the device is inserted at an angle via the second insertion method of Kuzma. As stated in the MPEP, "[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." (*See*, Manual of Patent Examining Procedure, § 2142.) For this reason, the Examiner's proposed combination is improper with regard to the second insertion method of Kuzma and should be reversed.

2. Substantial modifications are needed in the device of Kuzma to combine it with Dutcher for the purpose asserted by the Examiner when the device is inserted at an angle via the second insertion method of Kuzma

As noted above, the Examiner alleges that "it would have been obvious… to include the mesh of Dutcher with the device of Kuzma, for the purpose of enhancing tissue ingrowth to firmly fix target tissue." (See, Supplemental Examiner's Answer, pg. 4; emphasis added.) However, Kuzma's device would need to be substantially modified in order to achieve this alleged benefit. The Supreme Court recognized that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some ***articulated reasoning with some rational underpinning to support the legal conclusion of obviousness***." (*See KSR*, 127 S.Ct. at 1741 (citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006); emphasis added.) Because achieving the alleged benefit proposed by the Examiner would require substantial modification of Kuzma's device when Kuzma's device is inserted at an angle, the Examiner has failed to provide this required reasoning with a rational underpinning when Kuzma's device is inserted at an angle via Kuzma's second insertion method.

As noted above, the Examiner does not clearly state where the netting of Dutcher would be placed on the Kuzma device in the proposed combination. Assuming for the sake of argument that the netting could be mounted on shoulder 19 (*see*, Kuzma, FIG. 1A, reproduced above) of Kuzma's device, when Kuzma's device is inserted at an angle, as shown in FIG. 5 of Kuzma, the full surface of shoulder 19 does not contact the surrounding bone structure. In that case, the mesh added to shoulder 19 would not be in contact with the bone structure so as to "firmly fix" the device to the bone structure unless, at a minimum, at least one tine 16 is removed and/or modified and head 18 is redesigned so that the mesh on shoulder 19 is in contact with the bone structure. For example, Kuzma would need to be modified to change either the thickness of a portion of head 18, or change the angle of shoulder 19 relative to the rest of the device, and do so in such a way that head 18 does not interfere with tines 16.

Thus, because the device of Kuzma would have to be substantially modified to achieve the purpose of the combination proposed by the Examiner, the Examiner has failed to provide an adequate reason to combine Kuzma and Dutcher when Kuzma's device is inserted at an angle via Kuzma's second method of insertion.

For this additional reason, the Examiner's proposed combination is improper with regard to the second insertion method of Kuzma.

V. CONCLUSION

Because the Examiner's reasoning in support of making the proposed combination of Kuzma and Dutcher is not adequate for either of the insertion methods described above, the rejections noted above should be reversed.

For the reasons noted above, Appellants submit that the pending claims define patentable subject matter. Accordingly, Appellants request that the Examiner's rejections of these claims be reversed and that the pending application be passed to issue.

Dated: November 24, 2009

Respectfully submitted,

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